

What is claimed is

1. A process for producing microspheres that contain active component within polymer spheres as releasable, comprises: preparing polymer solution or dispersion having at least active agent, solvent or dispersant, and polymer;
5 drop-wise spitting the polymer solution or dispersion into a flowing fluid, at a predetermined temperature, as to form microsphere precursors; and allowing transfer of the solvent or dispersant within the microsphere precursors to the fluid
10 on way of transporting the microsphere precursors held in the flowing fluid.

2. A process for producing microspheres according to claim 1, wherein the fluid is lipophilic one if the polymer is hydrophilic; and the fluid is hydrophilic one if the polymer
15 is lipophilic.

3. A process for producing microspheres according to claim 1 or 2, wherein the fluid is on before hand cooled under a predetermined temperature.

4. A process for producing microspheres according to
20 anyone of claims 1-3, wherein the drop-wise spitting of the polymer solution or dispersion is made continuously with low flow rate as to form the liquid drops, or intermittently by each small amount at a predetermined interval.

5. A process for producing microspheres according to
25 anyone of claims 1-4, wherein the spitting of the polymer

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solution or dispersion is made in a manner to form a predetermined angle in a range of 45-90 degree between a flowing direction of the flowing fluid and a direction of the spitting.

6. A process for producing microspheres according to
5 anyone of claims 1-5, wherein the spitting is made through a nozzle.

7. A process for producing microspheres according to anyone of claims 1-6, wherein average diameter of the microspheres is in a range of 0.0001-5000 micro meter.

10 8. A process for producing microspheres according to anyone of claims 1-7, wherein the active component is comprised of at least one pharmaceutical substance having physiological function.

9. A process for producing microspheres according to
15 anyone of claims 1-8, wherein the polymer is at least one selected from a group consisting of: polyvinyl alcohol, polymethyl methacrylate, polyester, polycarbonate, polyurethane, polyurea, polyamide, poly alkylene oxalate, homopolymers of hydroxycarboxylic acids, copolymers of hydroxycarboxylic acids,
20 polyamino acids, cellulose derivatives, dextran derivatives, gelatin, shellac, waxes, chitin, and chitosan.

10. A process for producing microspheres according to anyone of claims 1-9, wherein average molecular weight of the polymer is in a range of about 1000-1000,000.

25 11. A process for producing microspheres according to

anyone of claims 1-10, wherein the polymer is in vivo degradable.

12. A process for producing microspheres according to anyone of claims 1-11, wherein the solvent or dispersant is at least one selected from a group consisting of: water, alcohols,
5 esters, halogenated hydrocarbons, ethers, aromatic hydrocarbons, hydrocarbons and ketones.

13. A process for producing microspheres according to anyone of claims 1-12, wherein the polymer solution or dispersion has a viscosity in a range of 50-10,000cP at 25°C.

10 14. A process for producing microspheres according to anyone of claims 1-13, wherein the predetermined temperature is in a range of 4-40°C.

15 15. A process for producing microspheres according to anyone of claims 1-14, wherein the fluid is a liquid that is at least one selected from water, alcohols, acetone, acetonitrile and liquid paraffins, and contains a surfactant at 0.1-10 weight-per-volume (W/V) %.

16. A process for producing microspheres according to anyone of claims 1-15, wherein flow rate of the flowing fluid
20 is a constant rate in a range of 0.1-500mL/minute.

17. An apparatus for producing microspheres that contain active component within polymer spheres as releasable, comprises; a main body in which a fluid flows or moves; a fluid supplier that sends out liquid as the fluid so that the liquid
25 moves or flows at a predetermined flow rate in the main body;

and a polymer solution spitter that drop-wise spits, into the fluid, the polymer solution or dispersion having at least active agent, solvent or dispersant, and polymer, at a predetermined temperature, as to form microsphere precursors; wherein the
5 solvent or dispersant within the microsphere precursors is transferred to the fluid on way of transportation of the microsphere precursors within the main body.

18. An apparatus for producing microspheres according to claim 17, wherein the fluid supplier has a tube through which
10 the fluid is sent out into the main body.

19. An apparatus for producing microspheres according to claim 17 or 18, wherein a plurality of said tubes are arranged in a predetermined interval.

20. An apparatus for producing microspheres according
15 to anyone of claims 17-19, wherein the polymer solution spitter has a nozzle so that direction of spitting the polymer solution or dispersant into the fluid makes a predetermined angle with a direction of flowing of the fluid.

21. An apparatus for producing microspheres according
20 to anyone of claims 17-20, wherein a plurality of said nozzles are arranged in a predetermined interval.

22. An apparatus for producing microspheres according to anyone of claims 17-21, further comprising a temperature keeper by which each of the main body, the fluid supplier and
25 the polymer solution spitter is kept at temperature in a range

of 4-40°C.

23. An apparatus for producing microspheres according to anyone of claims 17-22, further comprising a reservoir for the polymer microspheres at beneath of the main body; and a stirrer for stirring the liquid within the reservoir, which contains the polymer microspheres.

24. An apparatus for producing microspheres according to anyone of claims 17-23, wherein the drop-wise spitting of the polymer solution or dispersion is made continuously with low flow rate as to form the liquid drops, or intermittently by each small amount at a predetermined interval; the fluid is lipophilic one if the polymer is hydrophilic; and the fluid is hydrophilic one if the polymer is lipophilic.

25. An apparatus for producing microspheres according to anyone of claims 17-24, wherein the spitting of the polymer solution or dispersion is made in a manner to form a predetermined angle in a range of 45-90 degree between a flowing direction of the flowing fluid and a direction of the spitting.

26. An apparatus for producing microspheres according to anyone of claims 17-25, wherein average diameter of the microspheres is in a range of 0.0001-5000 micro meter.